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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/799,536	03/11/2004	Leah E. Appel	PC10270B	7842

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PFIZER INC.
PATENT DEPARTMENT, MS8260-1611
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GROTON, CT 06340

EXAMINER	
TRAN, SUSAN T	

ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 02/02/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/799,536	APPEL ET AL.	
	Examiner	Art Unit	
	Susan T. Tran	1615	

-- *The MAILING DATE of this communication appears on the cover sheet with the correspondence address* --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 49-78 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 49-78 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 3/11,3/29,4/26/04.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Receipt is acknowledged of applicant's Preliminary Amendment and Information Disclosure filed 03/11/04, Information Disclosure filed 03/29/04 and 04/26/04.

Claim Objections

Claims 49-62 are objected to because of the following informalities:

It appears that the word "and" in line 5 should read "or", because throughout the specification discloses x-ray diffraction analysis *or* differential scanning calorimetry (see for example page 4). Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 66-68 and 71 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. It appears that applicant's specification does not provide support for the limitation "meltable excipient" recites in claims 66 and 67. For examining purpose, it is being interpreted as any pharmaceutically acceptable excipient. Further clarification is suggested.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 49-68 and 70-77 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 2, 4, 15-45, 47-49 and 51-67 of U.S. Patent No. 6,706,283 ('283). Although the conflicting claims are not identical, they are not patentably distinct from each other because the '283 patent claims a controlled release dosage form, comprising: (a) a core comprising an osmotic agent and a low solubility drug in the form of a solid dispersion of said drug in a dispersion polymer, at least a major portion of said drug being amorphous; (b) a water-permeable coating around said core having at least one delivery port therein, said coating controlling the influx of water to said core from an aqueous environment of use to cause extrusion of at least a portion of said core through said at least one delivery port to said aqueous environment of use, said coating being non-dissolving and non-eroding during release of said drug; wherein said osmotic agent comprises a water-swellable hydrophilic polymer that is separate from said dispersion polymer; wherein

said dosage form provides an AUC in a use environment that is at least 1.25-fold that of a control dosage form comprising an identical dosage form containing an equivalent quantity of undispersed drug; and wherein said drug in said solid dispersion exhibits non-crystalline character in x-ray diffraction analysis. Cellulosic polymer including hydroxypropylmethyl cellulose acetate succinate (hpmcas) is found in claims 16, 30 and 48. The dosage form can be in the form of a bead (multiparticulate) is found in claims 17 and 52. The osmotic agent and the solid dispersion are in respective discrete portions, or is in first or second layer is found in claims 19-21. Therefore, one of ordinary skill in the art would expect the same controlled release osmotic dosage form results from the use of the instant invention given the claims of '283. There are no unusual and/or unexpected results, which would rebut prima facie obvious. As such, the instant claims would have been obvious given the claims of '283, which set out a similar controlled release osmotic dosage form using the same ingredients, conditions, and techniques as claimed herein.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 49-57, 60-72 and 76-78 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ayer et al. US 5,035,897, in view of Baichwal US 5,773,025.

Ayer teaches a dosage form for delivering soluble or insoluble drug comprising dosage form **10** comprises a wall **12** with at least one passage way **13**, and is non-erodible, which surround the internal compartment **14** (core) comprising granule **15** (see Figs 1-4, columns 3-4; and column 7, lines 1-22). Granule **15** comprises a homogenous blend of a drug **17** and granule forming ingredients **18** (column 3, lines 40-48). The drug is dispersed in binder, such as cellulosic ether polymer using solvent method, and the solvent is removed by spraying-drying (column 10, lines 26-44). The dosage form further comprises an expandable displacement member **20** (osmotic agent) in separate portion of the dosage form, wherein the member **20** comprises a hydrogel composition including swellable hydrophilic polymers, such as polyvinyl pyrrolidone, carboxymethyl cellulose, and tragacanth (Figs. 3-4, and column 9, lines 23-68).

Ayer is silent as to the teaching of the majority portion of the drug being amorphous.

Baichwal teaches a sustained release solid dosage form comprising agglomerated particles of a low solubility drug, a gelling agent, an ionizable gel strength-enhancing agent (osmotically effective solute), and an inert diluent (see abstract; and column 3, lines 13-43). Drug is particularly preferred in amorphous form, such as amorphous particle (column 4, lines 33-39). Baichwal also teaches the amorphous drug is dispersed into a solid, water soluble carrier to form a solution or dispersion that is thereafter rendered solid to for a solid dispersion, and can be

prepared by the melting (fusion), solvent or melting-solvent method (column 6, lines 49 through column 8, lines 1-19). Thus, it would have been obvious for one of ordinary skill in the art to modify the dosage form of Ayer using drug in amorphous form in view of the teaching of Baichwal, because Baichwal teaches the use of medicament in amorphous form to achieve high bioavailability of insoluble drug (column 3, lines 9-18), because Baichwal insoluble drug is rendered more bioavailable by dispersing into solid carrier using known method including solvent method similar to Ayer (column 6, lines 49-67).

Regarding claim 63, Ayer does not teach multiparticulate comprising core surrounded by a water permeable coating. However, Baichwal teaches granule of medicament/wetting agent/sustained release excipient is coated with hydrophobic material (column 11, lines 49-55). Thus, it would have been obvious for one of ordinary skill in the art to prepare the dosage form of Ayer in particulate form in view of the teaching of Baichwal, because Ayer teaches the dosage form can be in any shape and size (column 3, lines 13-16).

It is noted that the cited references do not teach the dosage form provides an AUC in a use environment that is at least 1.25 fold that of a control dosage form comprising an identical dosage form containing an equivalent quantity of undispersed drug. However, it is the position of the examiner that the dosage form of Ayer in combination with Baichwal would provide a similar AUC because the cited references recognize the advantageous results of dispersing the insoluble drug in a polymer to provide sustained/controlled release rate, and achieve high bioavailability.

Claims 58, 59 and 73-75 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ayer et al. US 5,035,897, in view of Baichwal US 5,773,025 and Kigoshi et al. US 6,254,889.

Ayer and Baichwal are relied upon for the above reasons. The cited references are silence as to the teachings of dispersion polymer such as hpmcas.

Kigoshi teaches a solid dispersion dosage form of amorphous drug, wherein in the solid dispersion, the drug is dispersed in polymer including hpmcas (see abstract, and column 3, lines 18-33). Thus, it would have been obvious for one of ordinary skill in the art to modify the dosage form of Ayer and Baichwal using the solid dispersion dosage form in view of the teaching of Kigoshi, because Baichwal teaches the use of medicament in amorphous form to achieve high bioavailability of insoluble drug (column 3, lines 9-18), because Ayer teaches dispersing drug in cellulosic polymer (column 10, lines 26-44), and because Kigoshi teaches the solid dispersion of amorphous drug can be formulated into granulating process, tabletting process, as well as coating process (column 5, lines 60 through column 6, lines 1-9).

Pertinent Arts

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Curatolo et al., Chen et al., Miyajima et al., Nakano et al., and Ghebre-Sellassie et al. are cited as of interest for the teachings of osmotic dosage form and solid dispersion dosage form.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan T. Tran whose telephone number is (571) 272-0606. The examiner can normally be reached on M-R from 6:00 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page, can be reached at (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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Patent Examiner
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